IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
BROWNSVILLE DIVISION

ORTHOPEDIC INSTITUTE OF RIO GRANDE VALLEY PA,

Plaintiff,

v. CIVIL CASE NO. _____

XAVIER BECERRA, SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES;

and

CHIQUITA BROOKS-LASURE, ADMINISTRATOR FOR THE CENTERS FOR MEDICARE AND MEDICAID SERVICES,

Defendants.

VERIFIED COMPLAINT

COMES NOW the Plaintiff, ORTHOPEDIC INSTITUTE OF RIO GRANDE VALLEY PA, a Texas professional association ("OIRGV" or "Plaintiff"), to sue the Defendants, XAVIER BECERRA as Secretary of the United States Department of Health and Human Services (HHS), and CHIQUITA BROOKS-LASURE as

Administrator for the Centers for Medicare and Medicaid services (CMS), alleging as follows:

I. NATURE OF ACTION

1. Plaintiff respectfully request the District Court to review the Defendants' Final Order in the following Office of Medicare Hearing and Appeals (OMHA) Appeal Case No.: 3-13522041327, Docket Number: M-24-4259. A true copy of the Final Order is attached hereto as Exhibit A.

2. Plaintiff is a duly licensed orthopedic practice which treats Medicare patients in and around Brownsville, Texas. In turn, Plaintiff seeks reimbursement of its fees for services rendered to Medicare beneficiaries from CMS, which is overseen by the HHS. CMS alleges that it overpaid Plaintiff and seeks to recoup that money (with interest thereon) commenced in 2022. Plaintiff, having exhausted the administrative appeal process pursuant to 42 C.F.R. Part 405, hereby seeks judicial review of the final agency decision in accordance to 42 C.F.R. § 405.1877.

II. JURISDICTION AND VENUE

3. This action arises under Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.*, the Administrative Procedure Act, 5 U.S.C. §§ 551 *et seq*.

4. This Court has jurisdiction over this action pursuant to 42 U.S.C. §

405(g) as applied to Medicare appeals by 42 U.S.C. §1395ff, which authorizes judicial review of a final agency decision of the Secretary.

5. The Plaintiff is filing suit after receiving a Final Order of the Secretary denying coverage of its Medicare claims and affirming an overpayment and, therefore, has exhausted its administrative remedies.

6. The amount-in-controversy is greater than $1,900.00 as set forth in 42 U.S.C. §§ 1395ff(b)(1)(E)(i) and 1395ff(b)(1)(E)(iii). *See also* 42 C.F.R. § 1006(d)(4); Fed. Reg. 67297, 67297 (September 29, 2023).

7. In accordance to Section 1878(f)(1) of the Social Security Act (the "Act") and 42 C.F.R. § 405.1877, this suit is timely filed within sixty (60) days of the date upon which the Plaintiff received CMS's final agency decision.

8. In general, where a party seeks judicial review of the CMS's final decision in the Medicare claims appeal context, venue is proper "in the district court of the United States for the judicial district in which the plaintiff resides, or has his principal place of business, or, if he does not reside or have his principal place of business within any such judicial district, in the United States District Court for the District of Columbia." 42 U.S.C. § 405(g); 42 U.S.C. § 1395ff(b)(1)(A).

9. Thus, venue is proper in the Brownsville Division of the United States

District Court for Southern District of Texas, as the Plaintiff conducts business within the jurisdictional territory of the Court and the cause of action arose in Brownsville, Texas.

III. THE PARTIES

10. Plaintiff, Orthopedic Institute of Rio Grande Valley PA, is a Texas professional association. OIRGV provides orthopedic medical services in its principal place of business at 1203 E. Alton Gloor Boulevard, Brownsville, Texas 78526.

11. OIRGV completed all necessary requirements to be a Medicare provider.

12. OIRGV is, and has been, enrolled in the Medicare program pursuant to a Medicare Enrollment Application submitted to Centers for Medicare and Medicaid Services, and, at all times relevant to this action, followed all applicable federal statutes and regulations and was enrolled as a provider of services in the Medicare program.

13. At all times relevant to this action, OIRGV billed Medicare for Medicare Part B services.

14. Defendant, Hon. Xavier Becerra, Secretary of Health and Human

Services, United States Department of Health and Human Services (the "Secretary"), maintains his principal office at 200 Independence Avenue SW, Washington, DC 20201. Secretary is being sued in his official capacity only.

15. HHS is the federal agency of the United States of America charged with overseeing the operation of the Medicare program.

16. Defendant, Hon. Chiquita Brooks-LaSure, Administrator, Centers of Medicare and Medicaid Services, Office of External Affairs, maintains her principal office at 7500 Security Blvd., Baltimore, MD 21244.

17. CMS operates and regulates the Medicare payment system nationwide. It also directs its contractors, who are responsible for the first two levels of administrative review of Medicare claim denials.

18. The Office of Medicare Hearings and Appeals (OMHA) generally conducts the third level in the Medicare claims appeal process and operates separately from the other contractors involved in the appeal process.

19. The Departmental Appeals Board (DAB) within the HHS provides the fourth level of administrative review.

20. References to the Secretary herein are intended to include CMS, its contractors, and any of their successors and/or predecessors.

IV. STANDARD OF REVIEW

20. A federal district court's review of a final decision of the Secretary as to Medicare coverage is limited to: (i) whether the Secretary's factual findings were supported by substantial evidence; (ii) whether the Secretary applied the proper legal standards; and (iii) whether the Secretary's decision was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 42 U.S.C. § 405(g); 5 U.S.C. § 706(2)(A); *Sternberg v. Sec'y, Dep't Health & Human Servs.*, 299 F.3d 1201, 1205 (10th Cir. 2002) (holding that the substantial evidence test is substantively the same as the review for arbitrariness or caprice); *Porzecanski v. Azar*, 316 F. Supp. 3d 11, 17 (D.D.C. 2018), aff'd, 943 F.3d 472 (D.C. Cir. 2019); *LivinRite, Inc. v. Azar*, 386 F. Supp. 3d 644, 652 (E.D. Va. 2019); *Becker v. Sebelius*, No. 12-cv-6177, 2014 WL 2711958, *1, *3 (D.N.J. June 13, 2014) (internal citations omitted).

21. Substantial evidence is "more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Richardson v. Perales*, 402 U.S. 389, 401 (1971) (internal quotation marks omitted); *see also Fratellone v. Sebelius*, No. 08-cv-3100, 2009 WL 2971751 *1, *9 (S.D.N.Y. Sept. 16, 2009) (citing *Murphy v. Sec'y of Health & Human Servs.*, 62 F. Supp. 2d 1104, 1106 (S.D.N.Y. 1999)).

22. While deferential, this review "is not a rubber stamp for the Secretary's decision and involves more than a search for evidence supporting the Secretary's findings." *Cook v. Heckler*, 750 F.2d 391, 393 (5th Cir. 1985) (citing *Tome v. Schweiker*, 724 F.2d 711, 713 (8th Cir. 1984)).

23. The court's factual review is limited to the administrative record. *See Mathews v. Weber*, 423 U.S. 261, 263, 270 (1976) (holding that under 42 U.S.C. § 405(g), the "court may consider only the pleadings and administrative record" and "neither party may put any additional evidence before the district court.").

24. However, the assessment of whether substantial evidence supports a decision of the Secretary requires the court to review the administrative record as a whole. This includes looking at evidence supporting the Secretary's position, as well as other evidence that detracts from it. *Alston v. Sullivan*, 904 F.2d 122, 126 (2d. Cir. 1990); *TNS, Inc. v. NLRB*, 296 F.3d 384, 395 (6th Cir. 2002); *Goffney v. Becerra*, 995 F.3d 737, 747 (9th Cir. 2021); 5 U.S.C. § 706. HHS "has codified [this] requirement in a regulation that directs the Office of Medicare Hearings and Appeals . . . to include in the record 'the appealed determinations, and documents and other evidence used in making the appealed determinations and the ALJ's or attorney adjudicator's decision,' as well as any proffered evidence excluded by

the adjudicator." *Goffney*, 995 F.3d at 747 (quoting 42 C.F.R. § 405.1042(a)(2)).

25. In contrast to the deference due to findings of fact, the Secretary's (or in this case Administrative Law Judge's ("ALJ")) conclusions of law as to Medicare coverage are reviewed *de novo*, and failure to apply the correct legal standards is grounds for reversal. 42 U.S.C. § 405(g); *see also Keefe*, 71 F.3d at 1062; *Pollard v. Halter*, 377 F.3d 183, 189 (2d Cir. 2004).

26. Pursuant to the Administrative Procedures Act ("APA"), the Secretary's final decision may also be set aside if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); *Palomar Med. Ctr. v. Sebelius*, 693 F.3d 1151, 1159 (9th Cir. 2012); *Porzecanski*, 316 F. Supp. 3d at 17; *LivinRite*, 386 F. Supp. 3d at 652.

27. To meet the requirements of the APA, an agency must "examine the relevant data and articulate a satisfactory explanation for its action." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009) (internal citations omitted).

28. In reviewing that explanation, the court "must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Motor Vehicles Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *see also Porzecanski*, 316 F. Supp. 3d

at 18.

29. An agency will have acted arbitrarily and capriciously where "the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *State Farm*, 463 U.S. at 43; *see also Porzecanski*, 316 F. Supp. 3d at 18.

30. The Court of Appeals for the D.C. Circuit has made clear that the propriety of an agency's decision is "a question of law, and only a question of law." *Marshall County Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993); *see also Embassy of Blessed Kingdom of God for All Nations Church v. Holder*, 6 F. Supp. 3d 559, 561 (E.D. Pa. 2014), aff'd sub nom.; *Embassy of Blessed Kingdom of God for All Nations Church v. Att'y Gen. U.S.*, 591 F. App'x 161 (3d. Cir. 2014) (citing *Marshall County* for the same); *Validus Reinsurance, Ltd. v. U.S.*, 786 F.3d 1039, 1042 (D.C. Cir. 2015).

V. MEDICARE PROGRAM

31. Congress enacted the Medicare Program in 1965 under Title XVIII of the Social Security Act to provide health insurance primarily to individuals sixty-

five years of age and older, disabled persons, and those with end-stage renal disease. Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (1965) (codified as amended at 42 U.S.C. §§ 1395-1396v).

32. The Medicare Program seeks to ensure that its beneficiaries have access to health care services. *Id.* at 286.

33. The Medicare Program is made up of four separate parts—Part A, Part B, Part C, and Part D.

34. Relevant to this matter, Medicare Part B refers to the supplementary medical insurance program authorized under Part B of Title XVIII of the Social Security Act. 42 U.S.C. § 1395k(a)(1); 42 C.F.R. § 400.202. Part B supplements Part A which includes diagnostic laboratory tests and other diagnostic tests. *See also* 42 C.F.R. § 410.10.

35. Providers and suppliers enroll in the Medicare Program by completing an application and undergoing a certification process to verify their licensing and other credentials. Providers and suppliers enroll with the Medicare Administrative Contractor ("MAC") for CMS to administer claims for the Medicare benefit category applicable to the provider or supplier's covered

services for the geographic locale in which the provider is physically located. 42 C.F.R. §§ 421.404(b)(1), (c)(1).

36. Under Medicare Part B, beneficiaries pay a monthly premium to receive coverage for the various forms of supplementary medical services that are enumerated at 42 U.S.C. § 1395x.

37. The U.S. District Court for the District of Columbia has expressly recognized that "Medicare Part B beneficiaries have a protected due process 'property interest' in 'receiving the medical insurance benefits for which they paid a monthly premium.'" *Bailey v. Mut. of Omaha Ins. Co.*, 534 F. Supp. 2d 43, 53–54 (D.D.C. 2008) (quoting *Gray Panthers v. Schweiker*, 652 F.2d 146, 148 n. 2 (D.C. Cir. 1980)).

38. While beneficiaries are the primary parties in interest to the Medicare Part B program, providers and suppliers are likewise parties in interest "as assignees of the beneficiaries." *Cervoni v. Sec'y, Health, Educ. & Welfare*, 581, F.2d 1010, 1018; 42 C.F.R. § 400.202; *see also Med-Cert Home Care, LLC v. Azar*, 365 F. Supp. 3d 742, 751 (N.D. Tex. 2019) (stating that "[p]recedent makes clear that [the provider] has a valid property interest in receiving Medicare payments for services rendered"); *A1 Diabetes & Med. Supply v. Azar*, 937 F.3d 613, 619 (6th Cir.

2019) (finding that the provider "plainly ha[d] a significant 'private interest': payment for services rendered").

39. The U.S. District Court has long recognized the rights of providers and suppliers under the Medicare Program, stating that "[t]he purpose of the Medicare [P]rogram is to reimburse providers for their reasonable costs." *Am. Med. Int'l, Inc. v. Sec'y, Health, Educ. & Welfare*, 466 F. Supp. 605, 626 (D.D.C. 1979).

40. In practice, when medical providers and suppliers, furnish services to a Medicare Part B beneficiary, the providers or suppliers thereafter submit a claim for reimbursement based on the beneficiary's assignment of their property interest to the provider or supplier.

41. Medicare providers and suppliers are statutorily entitled to reimbursement for services rendered to Medicare Part B beneficiaries under 42 U.S.C. § 1395l.

42. Providers and suppliers submit these claims for reimbursement to a MAC. 42 U.S.C. § 1395ff(a)(2)(A). As discussed in Section V.A.1 below, MACs are government contractors responsible for processing Medicare claims and making payments. 42 U.S.C. §§ 1395kk-1(a)(3).

A. Entities Involved in Medicare Claims Appeal Process

43. While CMS is the HHS agency responsible for administering the Medicare Program, CMS has contracted with various private entities to assist CMS in processing and auditing claims for reimbursement, and in the appeals process itself.

1. Medicare Administrative Contractors

44. CMS contracts with MACs to process and audit claims that have been submitted by Medicare providers for payment in a particular geographic jurisdiction of the country. 42 U.S.C. § 1395kk-1(a).

45. By statute, CMS is authorized to "enter into contracts with any eligible entity to serve as a [MAC.]" *Id.* at § 1395kk-1(a)(1).

46. MACs are statutorily authorized to perform the following functions: (i) determining the amount of reimbursement to providers and suppliers; (ii) paying such reimbursements to the applicable provider or supplier; (iii) providing education and assistance to Medicare Part A and B beneficiaries; (iv) providing consultative services to institutions, agencies, and others regarding maintenance of fiscal records necessary for reimbursement; (v) communicating with providers and suppliers regarding instructions from CMS; (vi) performing

functions related to provider education, training, and technical assistance; (vii) developing LCDs, which are determinations "under [P]art A or [P]art B, as applicable, respecting whether or not a particular item or service is covered . . . under such parts" for the geographic zone assigned to the MAC; (viii) overseeing an improper payment outreach and education program; and (ix) such other functions as are necessary or as specified in CMS's agreement with the MAC. *Id.* at §§ 1395kk-1(a)(4), 1395ff(f)(2)(B); 42 C.F.R. §§ 421.100, 421.200, 421.400.

47. In addition, MACs handle provider and supplier enrollment, as well as redeterminations, which form the first level of the Medicare claims appeal process. 42 C.F.R. §§ 421.200, 421.404.

48. Each MAC is designated to perform its duties for a specific geographic jurisdiction of the country. *See* 42 C.F.R. § 421.400(a); *see also* CMS, "Who are the MACs," (Dec. 1, 2021), available at: https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Who-are-the-MACs#MapsandLists.

49. Despite being jurisdictionally bound, MACs are required to follow federal statutes, regulations, and CMS program guidance.

50. A MAC may be held liable to the United States for a Medicare

payment if, in connection with such payment, the MAC acted with "reckless disregard" of its obligations under its Medicare administrative contract. 42 U.S.C. § 1395kk-1(d)(3).

51. Where a MAC—or director, officer, or employee of the MAC—is made party to a judicial or administrative proceeding arising from or relating directly to the Medicare claims appeal process, the Secretary may not indemnify the MAC if liability is determined to be criminal in nature, fraudulent, or grossly negligent. *Id.* at § 1395kk-1(d)(4).

52. CMS structures its contracts with MACs as "cost-plus-award-fee" contracts, which are a type of cost-reimbursement contract allowing an agency to provide incentives to contractors if they achieve specific performance goals. *See e.g.*, CMS, "Fact Sheet: Award of Medicare Administrative Contractor (MAC) Contract for Jurisdiction J" (Sept. 2014), available at: https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Downloads/Award-Background-J-J-Sept-2014.pdf; *see also* 42 U.S.C. § 1395kk- 1(b)(1)(D)(i).

53. Specifically, CMS is required to provide incentives to MACs to reduce improper payment error rates in their jurisdictions, which may include:

(i) a sliding scale of award fee payments and additional incentives to MACs that reduce the improper payment rates in their jurisdictions to certain thresholds, or accomplish tasks that further improve payment accuracy; or (ii) substantial reductions in award fee payments under cost-plus-award-fee contracts for MACs that reach an upper end improper payment rate threshold, or fail to accomplish tasks that further improve payment accuracy. *Id.* at § 1395kk-1(b)(1)(D)(ii)–(iii).

54. In addition, CMS is statutorily mandated to use specific claims payment error rates or similar methodologies in processing and reviewing Medicare claims in order to give MACs an incentive to implement effective education and outreach programs to providers and suppliers. *Id.* at § 1395kk-1(f).

2. Zone Program Integrity Contractors and Unified Program Integrity Contractors

a. ZPICs

55. Payment decisions made by MACs had been commonly audited by Zone Program Integrity Contractors ("ZPICs") through 2016, and presently by Unified Program Integrity Contractors, in a process referred to as a "post-payment review" of certain healthcare providers. 42 C.F.R. § 421.304 *et seq*.

56. In accordance with 42 U.S.C. § 1395ddd, as amended by Title II § 202 of the Health Insurance Portability and Accountability Act ("HIPAA") of 1996,

CMS was authorized to contract with ZPICs to fulfill program integrity functions for the Medicare Program.

57. ZPICs were a form of Recovery Audit Contractor ("RAC") under 42 U.S.C. § 1395ddd, and were charged with performing benefit integrity activities aimed to reduce fraud, waste, and abuse in the Medicare program. 42 U.S.C. § 1395ddd.

58. The contract between CMS and a ZPIC specified the functions the ZPIC was to perform, and included any or all of the following functions: (i) conducting medical reviews, utilization reviews, and reviews of potential fraud related to activities of providers and other individuals furnishing services for which Medicare payment may have been made either directly or indirectly; (ii) auditing, settling and determining cost report payments for providers of services, or other individuals or entities, as necessary to help ensure proper Medicare payment; (iii) determining whether a payment was authorized under 42 U.S.C. § 1395y(b) and recovering mistaken and conditional payments therefrom; (iv) educating providers, suppliers, beneficiaries, and others regarding payment integrity and benefit quality assurance issues; and (v) developing, and periodically updating, a list of items of durable medical equipment that were

frequently subject to unnecessary utilization throughout the ZPIC's entire service area, in accordance with 42 U.S.C. § 1395m(a)(15). 42 U.S.C. § 1395ddd(b); 42 C.F.R. § 421.304; MPIM, CMS Pub. 100-08, Ch. 4, § 4.2.2.1.[1]

59. One of the tools that ZPICs, and other Medicare contracting entities, use in performing their duties is statistical sampling and extrapolation, as described in the MPIM. 42 U.S.C. § 1395ddd; *see also* MPIM Ch. 8, § 8.2 (noting that "[i]f a large number of claims are involved, contractors consider using statistical sampling for overpayment estimation to calculate the amount of the overpayment."). However, in order for the Defendants to utilize statistical sampling, a strict adherence to the MPIM requirements is required. This is so because the statistical sampling and extrapolation of overpayment for unexamined claims is, in essence, a deprivation of the provider's due process rights. Thus, unless Defendants sustain the burden that it has satisfied all elements of the MPIM, chapter 8, the statistical sampling and overpayment estimation must be invalidated.

60. ZPICs were tasked with identifying both overpayments and underpayments. *See e.g.*, 42 U.S.C. §§ 1395ddd(b) and (h), 1395g(a); 42 C.F.R. §

[1] Unless otherwise noted, citations to the MPIM are to the 2011 version, which was the version in effect at the time of the audit.

421.304; MPIM Ch. 8, §§ 8.4.1.3, 8.4.4.4.4, 8.4.5.2, 8.4.7.1.

61. Each ZPIC was designated to perform its duties for a specific geographic jurisdiction of the country. *See e.g.*, HHS, Office of Inspector General ("OIG"), "Enhancements Needed in the Tracking and Collection of Medicare Overpayments Identified by ZPICs and PSCs," OEI-03-13-00630, at 2 (Sept. 2017).

62. ZPICs—and their employees and professional consultants—were only protected from criminal or civil liability in regard to the program integrity activities they performed under their contracts with CMS so long as they exercised due care in carrying out these activities. 42 C.F.R. § 421.316(a); MPIM Ch. 4, § 4.2.2.4.

63. ZPICs were awarded task orders which specified the requirements for the benefit integrity work that the ZPIC would perform. The task order which covered detecting, deterring, and preventing fraud, waste and abuse within the ZPICs jurisdiction allowed for the ZPIC to be paid on a "fee for service" basis. *See e.g.*, HHS, OIG, "Enhancements Needed in the Tracking and Collection of Medicare Overpayments Identified by ZPICs and PSCs," OEI-03-13-00630, at 3; Government Accountability Office ("GAO"), *Decision in re Cahaba Safeguard Administrators, LLC*, B-401842.2, at 2 (Jan. 25, 2010).

64. In addition to their fixed contractual rate compensation, ZPICs could also be awarded additional fees per task order per year to recognize high quality of service and administrative actions. GAO, "Report to Congressional Requesters - Medicare Program Integrity: Contractors Reported Generating Savings, but CMS Could Improve Its Oversight," GAO-14-111, at 12 (Oct. 2013); *see also* CMS, "Medicare Integrity Program (MIP) ZPIC Zone 5 Task Order 0001 Award Fee Plan," *available at*: https://sam.gov/opp/81f6cb481f907f70c66525b3300c3191/view#attachments-links.

b. UPICs

65. In the Fiscal Year 2016, CMS began transitioning from ZPICs to Unified Program Integrity Contractors ("UPICs"). *See* CMS, Fiscal Year 2016: Justification of Estimates for Appropriations Committees, at 205.

66. As with ZPICs, UPICs are a form of RAC under 42 U.S.C. § 1395ddd, and CMS is authorized to contract with UPICs to fulfill program integrity functions for the Medicare Program. 42 U.S.C. § 1395ddd.

67. The UPIC is authorized to: (i) prevent fraud by identifying program vulnerabilities; (ii) proactively identify incidents of potential fraud, waste, and abuse that exist within its service area and take appropriate action; (iii) investigate

allegations of fraud; (iv) explore available sources of fraud leads in its jurisdiction; (v) initiate appropriate administrative actions where there is reliable evidence of fraud, including, but not limited to, payment suspensions and revocations; and, (vi) refer any necessary provider or supplier outreach to the provider outreach and education staff at the MAC. 42 U.S.C. § 1395ddd(b); 42 C.F.R. § 421.304; 42 C.F.R. § 405.371(a)(1); MPIM Ch. 4, § 4.2.2.1.

68. UPICs—and their employees and professional consultants—are only protected from criminal or civil liability in regard to the program integrity activities they perform under their contracts with CMS so long as they exercise due care in carrying out these activities. *Id.* at § 421.316(a); MPIM Ch. 4, § 4.2.2.4.

69. UPICs are tasked with identifying both overpayments and underpayments. *See e.g.*, 42 U.S.C. §§ 1395ddd(b) and (h), 1395g(a); 42 C.F.R. § 421.304; MPIM Ch. 8, §§ 8.4.1.3, 8.4.4.4.4, 8.4.5.2, 8.4.7.1.

70. As with ZPICs, each UPIC is designated to perform its duties for a specific geographic jurisdiction of the country. *See e.g.*, CMS, "Review Contractor Directory - Interactive Map" (Dec. 1, 2021), *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-

Interactive-Map.

71. UPICs are awarded one of CMS's five UPIC multiple-award indefinite-delivery, indefinite-quantity ("IDIQ") contracts for the five UPIC geographic jurisdictions, and these IDIQ contracts contemplate a "cost plus award fee" payment model. *See e.g.*, GAO, *Decision in re AdvanceMed Corp.*, B-415360; B-415360.2; B-415360.3, at 2 (Dec. 19, 2017); CMS, "UPIC Jurisdiction 1 Task Order, Statement of Work," at 1, *available at*:

https://sam.gov/opp/c5df515b5cf3afcb0d8fcd4e20c7acba/view#attachments-links.

72. Generally, UPICs are paid a base fee in addition to an award fee that is awarded based on quality (e.g., accuracy, timeliness, and efficiency in performing tasks), management (i.e., how the UPIC communicates and coordinates with stakeholders), and certain other areas, such as innovation and value-added work. *See* CMS, "UPIC Jurisdiction 1 Award Fee Plan," at 2–3, 6, *available at*:

https://sam.gov/opp/c5df515b5cf3afcb0d8fcd4e20c7acba/view#attachments-links.

73. In addition, starting in year two of a contract or task order, the UPIC has the potential for an "Excellence Award" that will be based on the Center for

Program Integrity ("CPI") reaching its Return on Investment ("ROI") and the UPIC itself achieving high marks in its evaluation. *Id.* at 9–11.

3. Qualified Independent Contractors

74. Under 42 U.S.C. § 1395ff, CMS is mandated to "enter into contracts with qualified independent contractors to conduct reconsiderations of [redetermination decisions.]" Contracts between CMS and qualified independent contractors ("QICs") are to last for an initial term of three years and are renewable on a triennial basis thereafter. 42 U.S.C. § 1395ff(c)(1).

75. A QIC is statutorily required to be independent of any MAC, ZPIC, or UPIC. *Id.* at § 1395ff(c)(2), (c)(3)(K). The QIC must perform such duties and functions and assume such responsibilities as may be required by CMS to carry out the Medicare claims appeal process, "and shall have sufficient medical, legal, and other expertise . . . and sufficient staffing to make reconsiderations[.]" *Id.* at § 1395ff(c)(3)(A).

76. Each QIC is designated to perform its duties for a specific geographic jurisdiction of the country or by type of service. *See e.g.*, CMS, "Second Level of Appeal: Reconsideration by a Qualified Independent Contractor," (June 23, 2022), *available a*t: https://www.cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/ReconsiderationbyaQualifiedIndependentContr

ator.

77. National coverage determinations ("NCDs"), CMS Rulings, Council decisions, and applicable laws and regulations are binding on the QIC. However, QICs are not bound by LCDs or CMS program guidance—though applicable regulations indicate that a QIC should "give substantial deference to these policies if they are applicable to a particular case." 42 U.S.C. § 1395ff(c)(3)(B)(ii)(I)–(II); 42 C.F.R. § 405.968(b)(1) – (2).

78. As with ZPICs and UPICs, QICs—and persons employed by or in a fiduciary relationship with a QIC—are only protected from criminal or civil liability in regard to the duties, functions, or activities they perform under their contracts with CMS so long as they exercise due care in carrying out these duties, functions, or activities. *Id.* at § 1395ff(c)(5).

79. Compensation provided by CMS to a QIC in connection with reconsideration reviews and decisions "shall not be contingent on any decision rendered by the [QIC] or by any reviewing professional." *Id.* at § 1395ff(c)(3)(K).

80. Similarly, any compensation provided by a QIC to a reviewer in connection with redetermination reviews and decisions must not be contingent on any decision rendered by the reviewer. *Id.* at § 1395ff(g)(3).

4. Administrative Law Judges

81. OMHA is responsible for the third level of the Medicare claims appeal process, whereby a reconsideration decision by the QIC is reviewed by an OMHA adjudicator, and an ALJ hearing can be requested. 42 U.S.C. § 1395ff(b)(1); 42 C.F.R. §§ 405.1000–48.

82. OMHA was created by the Medicare Modernization Act of 2003 in an effort to make the appeals process more efficient, and OMHA is functionally and organizationally independent of CMS. *See* Pub. L. No. 108-173, 117 Stat. 2066 (2003); *see also* CMS, MLN006562, Medicare Parts A & B Appeals Process (May 2021).

83. A hearing may be requested before an ALJ under the regulatory requirements included at 42 C.F.R. § 1000.1014 where the request for hearing is filed within sixty calendar days after receipt of the notice of the QIC's reconsideration decision and so long as the amount in controversy requirement is met. 42 C.F.R. §§ 405.1002, 405.1006.

84. The purpose of a hearing before an ALJ is to provide important procedural due process protections to an appellant-provider, including "the opportunity to have a live hearing, present testimony, submit written statements

of law and fact, and cross-examine witnesses." *Med- Cert*, 365 F. Supp. 3d at 753 (citing *Family Rehab., Inc. v. Azar*, 886 F.3d 496, 499 (5th Cir. 2018).

85. In contrast, the Council "may, but is not required to conduct additional proceedings, including a hearing." *Med-Cert*, 365 F. Supp. 3d at 753.

86. The ALJ reviews an appeal under a *de novo* standard, which is less deferential than the standard of review applied by a district court. *Id.* at 754; *see also Am. Hosp. Ass'n v. Burwell*, 812 F.3d 183, 191 (D.C. Cir. 2016) (concluding that a district court's review would be more deferential than an ALJ's *de novo* review in the Medicare claims appeal process).

87. Where a provider or supplier disagrees with how a statistical sample and/or extrapolation was conducted, the provider or supplier must assert the reasons they disagree with how the statistical sampling and/or extrapolation was conducted in the request for an ALJ hearing. 42 C.F.R. § 405.1014(a)(3).

88. CMS has made clear that this requirement to include the reasons for disagreement with how the statistical sample and/or extrapolation was conducted "does not limit the appellant's ability to provide additional information or arguments during the course of the appeal." Rather, the requirement exists to "provide the adjudicator with information on the appellant's basis for the appeal

and is necessary to evaluate the record[.]" 82 Fed. Reg. 4974, 5033 (Jan. 17, 2017).

89. The ALJ is required to conduct "a *de novo* review" and to issue a decision "based on the administrative record, including . . . any hearing record." 42 C.F.R. § 1000(d).

90. The ALJ's decision "must be based on evidence offered at the hearing or otherwise admitted into the record, and shall include independent findings and conclusions." *Id.* at § 405.1046(a)(1). Further, the ALJ's decision may not be based on extra-record documents. *Id.*

91. CMS has explained that the "independent findings and conclusions" requirement is intended to express the requirement for *de novo* review and prohibits the ALJ from "merely incorporat[ing] the findings and conclusions offered by others" at the redetermination or reconsideration level. 82 Fed. Reg. 4974 at 5082, 5084.

92. In addition to the specific reasons for the decision and a summary of any clinical or scientific evidence used in making the decision, the ALJ's decision must also include, "for any new evidence that was submitted for the first time at the OMHA level . . . a discussion of the new evidence[.]" 42 C.F.R. § 405.1046(a)(2)(i)–(ii).

93. ALJ decisions have been vacated where the ALJ's decision did not address relevant evidence, such as expert reports, and/or hearing testimony relevant to statistical sampling and extrapolation. *See e.g., Strategic Ambulance (Appellant) (Beneficiaries) Palmetto GBA (Contractor) Claim for Supplementary Medical Insurance Benefits (Part B)*, No. M-10-770, 2012 WL 1980570 (H.H.S. Mar. 19, 2012); *Jackson Healthcare (Appellant) (Beneficiary) Cahaba GBA (Contractor) Claim for Hospital Insurance Benefits (Part A)*, No. M-11-259, 2012 WL 889345 (H.H.S. Jan. 25, 2012) (reversing the ALJ's decision for neglecting to evaluate the testimony of two experts in its decision); *Simon Becker, DPM (Appellant) (Beneficiary) Safeguard Services (PSC) (Contractor) Claim for Supplementary Medical Insurance Benefits (Part B)*, No. M-11- 1657, 2011 WL 7007042 (H.H.S. Aug. 17, 2011) (stating that "the ALJ's failure to provide any meaningful analysis or specific reasons for his decision with respect to sampling does not result in a decision that is calculated to be understood" as required by applicable regulations).

94. In issuing a decision, ALJs are bound by all laws and regulations pertaining to the Medicare program, including Title XVIII of the Social Security Act and applicable implementing regulations. CMS Rulings, precedential Council decisions, and NCDs are likewise binding on the ALJ. 42 C.F.R. § 405.1063.

95. ALJs are not bound by LCDs or CMS program guidance, but will give substantial deference to these policies if they are applicable to a particular case. *Id.* at § 405.1062(a).

96. The ALJ must consider "all the issues for the claims . . . specified in the request for hearing that were brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in [the appellant's] favor." *Id.* at § 405.1032(a).

97. Where an appellant "asserts a disagreement with how a statistical sample and/or extrapolation was conducted in the request for hearing . . . in deciding issues related to how [the] statistical sample and/or extrapolation was conducted, the ALJ or attorney adjudicator must base his or her decision on a review of the entire sample to the extent appropriate to decide the issue." *Id.* at § 405.1032(d).

98. In conjunction with its review and decision, the ALJ has a regulatory duty to build the administrative record. This administrative record must include the originally-appealed decisions, the documents and other evidence used in making those appealed decisions, the ALJ's decision, and all other evidence. *Id.* at § 405.1042(a).

99. OMHA's ALJs have also been granted the authority to compel CMS and its contractors to produce documents related to the issues that are before an ALJ. Specifically, "[i]f an ALJ . . . believes that the written record is missing information that is essential to resolving the issue on appeal and that information can be provided only by CMS or its contractors, the information may be requested from the QIC that conducted the reconsideration or its successor." *Id.* at§ 405.1034(A). Missing information that "can be provided only by CMS or its contractors" is information that "is not publicly available, is not in the possession of, and cannot be request and obtained by one of the parties." *Id.* at § 405.1034(a)(2). It is also within the authority of ALJs to issues subpoenas to require entities—including those not party to an ALJ hearing—to produce existing documents. *Id.* at § 426.405(c)(11).

100. Relatedly, the Fifth Circuit Court of Appeals has held that the effectuation of a final agency decision is "inextricably intertwined" with the agency's initial action and thus making effectuation an essential component of resolving ALJ appeals. *D&G Holdings, LLC v. Becerra*, 22 F.4th 470 (5th Cir. 2022).

101. Effectuation includes an accounting of the amount of payment owed by a provider. Federal courts have made clear that "[i]t is inexcusable that the

Secretary would allow [a MAC] to wield the sovereign authority of the United States to seize money from a private company but then be utterly unable to give an accounting for the amount pillaged." *D&G Holdings, LLC v. Azar*, 776 F. App'x 845, 848 (5th Cir. 2019).

102. Given the regulatory authority granted to ALJs, it is in the purview of an ALJ to require that CMS or its contractor perform a full accounting of a provider's debts where missing documentation regarding the total amount recouped can only be provided by CMS or its contractors.

103. The ALJ's decision on a request for hearing is binding on all parties unless "a party requests a review of the decision by Council within the stated time period or the Council reviews the decision issued by an ALJ . . . and the Council issues a final decision . . . or the appeal is escalated to Federal district court under the provision at [42 C.F.R.] § 405.1132[.]" 42 C.F.R. § 405.1048(a)(1).

5. Medicare Appeals Council

104. Where a party is dissatisfied with the ALJ's decision, that party may appeal the ALJ's decision up to the Council, and the Council is statutorily authorized to review the ALJ's decision. 42 U.S.C. § 1395ff(b)(1)(A); 42 C.F.R. §§ 405.1100(a), 405.1102(a)(1).

105. In reviewing the ALJ's decision, the Council is required to undertake a *de novo* review. 42 C.F.R. § 405.1100(c). In conducting its review *de novo*, the Council must consider all of the evidence in the administrative record. *Id.* at §§ 405.1108(a), 405.1122(a)(1).

106. As with ALJs, in conducting its review, the Council is bound by all laws and regulations pertaining to the Medicare program, including Title XVIII of the Social Security Act and applicable implementing regulations. CMS Rulings, precedential Council decisions, and NCDs are likewise binding on the Council. *Id.* at § 405.1063.

107. The Council is not bound by LCDs or CMS program guidance, but will give substantial deference to these policies if they are applicable to a particular case. *Id.* at § 405.1062(a).

108. In reviewing an ALJ's decision, the Council will issue a final decision or dismissal order or remand a case to the ALJ within 90 calendar days of receipt of the appellant's request for review, unless that period is extended. *Id.* at §§ 405.1100(c), 405.1108(a); 405.1128.

109. Where the Council issues a decision, that decision will act as the final decision of the Secretary for purposes of 42 U.S.C. § 405(g) and § 1395ff(b)(1)(A)

and is final and binding on all parties unless a federal district court issues a decision modifying the Council's decision. 42 C.F.R. § 405.1130.

B. Medicare Administrative Appeals Process

110. If a Medicare provider wishes to appeal a ZPIC determination, or any post-payment claim denial, they are subject to the lengthy appeals process set forth in 42 U.S.C. § 1395ff. The Medicare appeals regulations allow for five levels of appeal as follows:

a. Level One: Redetermination

111. After the initial determination that an overpayment has been made, a denied claim may be submitted to a MAC for redetermination. 42 U.S.C. § 1395ff(a)(3)(A). In the case of a denied claim by a ZPIC, the determination is sent back to the MAC for re-review.

112. Upon receipt of the request for redetermination, the MAC has sixty days to issue a decision. *Id.* at § 1395ff(a)(3)(C)(ii).

2. Level Two: Reconsideration

113. If the redetermination is unfavorable, the appealing party may submit a request for reconsideration. *Id.* at §§ 1395ff(b), (c).

114. A reconsideration is a review of the MAC's redetermination

conducted by a QIC. *Id.* at §1395ff(c)(B)(i).

115. Upon receipt of the request for reconsideration, the QIC has sixty days to issue a decision. *Id.* at § 1395ff(c)(3)(C)(i).

3. Level Three: ALJ Hearing

116. A party that is dissatisfied with the QIC's reconsideration may request a hearing and *de novo* review before an ALJ with OMHA, provided the amount in controversy is met. *Id.* at § 1395ff(b)(1)(E).

117. The requisite minimum amount in controversy at the time OIRGV requested an ALJ hearing in the Calendar Year 2023 was $180. CMS, Medicare Program; Medicare Appeals; Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2015, 79 Fed. Reg. 57933, 57934 (Sept. 26, 2014).

118. Under 42 U.S.C. § 1395ff(d)(1)(A), the ALJ must conduct and conclude the hearing and render a decision no later than 90 days after the request for a hearing was filed. *See also* 42 C.F.R. § 405.1016(a).

4. Level Four: Medicare Appeals Council Review

119. The final administrative option for appeal of an unfavorable decision occurs with the Council. 42 U.S.C. § 1395ff(d)(2); 42 C.F.R. § 405.1108(a).

120. The Council, under the authority of 42 C.F.R. § 405.1110, on its own motion, may review the ALJ's decision.

121. Under 42 C.F.R. § 405.1100(c), Council undertakes a *de novo* review and issues a decision, dismissal or remands the case to the ALJ within 90 days.

5. Level Five: Federal District Court

122. Pursuant to 42 C.F.R. § 405.1136(a)(1) and (b)(1), a party to the Council decision may obtain a federal district review.

123. § 405.1136(f) provides a substantial evidence standard of review.

V. FACTUAL BACKROUND AND PROCEDURALHISTORY

124. OIRGV seeks judicial review of the Secretary's overpayment demand assessed on claims submitted by OIRGV, and previously paid by Medicare, for dates of service between September 11, 2020 and December 7, 2021.

A. UPIC's Post-Payment Review

125. In July of 2022, CMS's UPIC, Qlarant Integrity Services ("Qlarant"), initiated a post-payment review and requested certain medical records from the Plaintiff. According to Qlarant's Statistical Sampling for Overpayment Estimation (SSOE) report, the universe of claims under review contained "all final paid claims and associated paid claim lines from Shared Systems Data, paid

by UPIC Southwest MACs, for which Orthopedic Institute of Rio Grande Valley, PA billed for claims paid between April 23, 2019 and April 22, 2022. Further, the universe was limited on claims in which one of the claim lines contained a paid procedure code equaled to Q4145, Q4155, Q4159, Q4162, Q4171, Q4173, Q4174, Q4177, Q4178, Q4180, Q4185, Q4186, Q4192, Q4206, Q4213, Q4215, Q4217, Q4231, Q4231, or Q4246. Railroad beneficiaries, previously adjusted claims on appeal where Region Code = 33, 57, or 67, claim lines for E&M codes, and claims where the Principal Diagnosis or Diagnosis 1 – 5 began with any of the following: L, T2, T31, T32, E0862, E1062, E1162, I8731, I8733, Z48817, or Z511 were excluded." Additionally, four claim which were previously reviewed by the RAC: 452220308902430, 452820317070780, 452820317070820, 452821097003610 were excluded for the review.

126. In total, 120 claims made up the universe of claims under audit.

127. Purportedly, from the 120-claim universe, Qlarant employed computer-generated statistical sample to select 30 sample claims for clinical review.

128. Plaintiff duly produced the requested medical records for the 30-claim review.

129. Upon Qlarant's clinical review of the 30-claim sample, it concluded an error rate of 100% and assessed a $395,458.00 extrapolated overpayment.

B. Level One: Redetermination

130. On April 21, 2023, OIRGV timely submitted a Request for Redetermination to the MAC to dispute both thirty (30) substantive claims and the corresponding SSOE.

131. On June 8, 2023, the MAC issued a fully unfavorable redetermination decision.

C. Level Two: Reconsideration

132. On December 1, 2023, OIRGV timely submitted a Request for Reconsideration to the QIC, C2C Solutions, Inc. ("C2C"), in response to the MAC's unfavorable redetermination decision.

133. OIRGV incorporated all arguments set forth in its prior redetermination request and further disputed all denied claims.

134. On February 16, 2024, C2C issued a fully unfavorable reconsideration decision, identified as Medicare Appeal Number 1-13522041327.

135. In its reconsideration decisions, C2C affirmed the extrapolated overpayment.

D. Level Three: ALJ Hearing

136. On April 15, 2024, OIRGV timely filed a Request for Hearing by an ALJ with OMHA to appeal C2C's unfavorable reconsideration decision.

137. On June 20, 2024, a telephonic hearing was held before ALJ Catherine R. Fuller ("ALJ Fuller") of the OMHA Cleveland Field Office. Attorney Ethan Lau, Dr. Mario Quesada (the treating physician), and Dr. Harold Haller (expert statistician) appeared on behalf of OIRGV.

138. On July 11, 2024, ALJ Fuller issued a partially favorable decision on the matter. (the "ALJ Decision"). A redacted copy of the ALJ Decision is attached as **Exhibit B**.

139. Upon full review of the administrative records and receiving live testimonies, ALJ Fuller held, among other things, that OIRGV "successfully demonstrated that the statistical sampling and extrapolation of overpayment is invalid." *Id.* at pg. 9. Furthermore, ALJ Fuller held that "the overpayment assessed is limited to the 30 claims subject to this decision and may not be extrapolated to the universe." *Id.*

140. In her decision, ALJ Fuller specifically noted that "CMS's guidelines for use of statistical sampling for overpayment estimation are found in MPIM,

chapter 8, section 8.4. The instructions are provided so that a sufficient process is followed when conducting statistically sampling to project overpayments. Failure by the audit contractor to follow one or more of the requirements contained in instructions does not necessarily affect the validity of the statistical sampling that was conducted or the projection of the overpayment. An appeal challenging the validity of the sampling methodology must be predicated on the actual statistical validity of the sample as drawn and conducted. MPIM §§ 8.4.1.1. and 8.4.1.2."

141. ALJ Fuller accurately noted that "Section 8.4.4.5 of the MPIM provides that the contractor shall maintain all documentation pertinent to the calculation of an estimated overpayment including but limited to the statistician-approved sampling methodology, universe, sampling frame and formal worksheets. The documentation must be sufficient to allow for any future replication and/or validation by an administrative or judicial body."

142. Upon examination, ALJ Fuller specifically found "preponderance of evidence supports invalidating the UPIC's statistical sampling and overpayment estimation." ALJ Fuller found that "the record lacks sufficient documentation of the actual universe of claims that UPIC and QIC relied on to create the sampling

frame." Under section 8.4.1.3 of the MPIM, ALJ Fuller reasoned, "one of the mandatory steps include defining the 'universe,' the 'sampling unit,' and the 'sampling frame.'" Section 8.4.3.2.1.B of the MPIM provides that "[t]he universe shall consist of all fully and partially paid submitted by the provider/supplier for the period of selected for review and for sampling units to be reviewed. For example, if the review is of Physician X for the period of January 1, 2002, through March 31, 2002, and laboratory and diagnostic tests have been selected for review, the universe would include all fully and partially paid claims for laboratory and diagnostic tests billed by that physician for the selected period time period."

143. ALJ Fuller properly concluded that the "actual universe is more encompassing of a set of clams based on provider, dates of services, and should include all claims falling withing these parameters to create the universe before multiple filters are applied."[2] Further, "the actual universe would include zero paid claims that are potential underpaid claims but were excluded from the universe file produced in this appeal." Also, "the MPIM requires all claim data used to create the universe is subject to the documentation requirements, even claim data excluded from the universe to establish the sampling frame."

[2] These filters pertain to the creation of the sampling frame for which the actual sample is drawn.

144. ALJ Fuller found that the UPIC's SSOE failed to comply with the MPIM's requirements. Specifically, "[t]he target universe that was produced [by the UPIC] only included claims identifying overpayments and excluded zero-paid claims from their audit review. The data produced defining the universe is no different than the data produced for the sampling frame."

145. Furthermore, the QIC acknowledged that zero-paid claims were excluded from the universe that was produced. ALJ Fuller opined that "[a] universe that includes all the zero-paid claims that were excluded and all claims from the review period would cure present deficiencies in this appeal." Consequently, ALJ Fuller aptly held that there was "insufficient documentation to support the validity of the extrapolated overpayment, as this failure deprived the Appellant a due process right to recreate and challenge the statistical sampling and extrapolation methodology."

E. Level Four: Medicare Appeals Council Review

146. On September 9, 2024, CMS, acting through the QIC, referred the ALJ Decision for an Own Motion Review by the DAB.

147. On November 26, 2024, the Council reversed the ALJ Decision and declined to extend Medicare coverage for the claims in question.

148. The Council's decision constitutes CMS' final agency order (the "Final Order").

VI. CAUSES OF ACTION

COUNT I

JUDICIAL REVIEW OF AGENCY DECISION

149. The allegations contained in paragraph 1 through 148 of this Verified Complaint are incorporated by reference as if fully set out herein.

150. The Defendants acted arbitrarily and capriciously by reinstating the flawed statistical sampling and extrapolated overpayment in its Final Order. Specifically, Defendants abused its discretion by predicating its overpayment demand on an administratively deficient SSOE. Defendants, through the UPIC, failed to comply with MPIM's specifications on its construction of the claim universe and maintenance of SSOE data documents.

151. As ruled by ALJ Fuller, the QIC failed to construct a valid target universe by unjustifiably excluding all zero-paid claims. As such, the resulting universe was unlawfully biased against the Appellant while it completely ignoring any underpayments attributable to the Defendants.

152. Furthermore, the document purported by QIC to contain the universe data information contained only identical information as the sampling frame. This

is clear violation of the MPIM. As noted by ALJ Fuller, "actual universe is more encompassing of a set of claims based on provider, dates of services, and should include all claims falling within these parameters to create the universe before multiple filters are applied." Given that the sampling frame was derived from the claim universe after certain filters in accordance to the audit parameters have been applied, it is an impossibility for the universe file to contain the identical data as the sampling frame file.

153. In *Good Creek Physical Medicine LLC v. Becerra*, Judge David C. Norton held that "[i]n cases where the provider was initially overpaid, the net overpayment identified in the sample is the projected to the sampling frame of that provider's claims to form the extrapolated overpayment amount. This process requires the contractor to accurately assess underpayments as well as overpayment, including claims that were unpaid after adjudication ('zero-paid claims') to ensure the actual net overpayment is correctly calculated." 2024 WL 3653697 *2. In sanctioning the government for violating an order to complete the administrative records, Judge Norton ruled that the proper "Universe File is the document that did not omit the zero-paid claims[.]" "This information operates as input to the subsequent calculated overpayment, and the Secretary's failure to

produce said information is a violation of the court's order to complete the administrative record[.]" *Id.* at *9.

154. In the present case, it is unequivocal that Defendants have either withheld or failed to maintain proper universe documentation to allow the Appellant or the court to validate and/or challenge the SSOE.

155. This violated the explicit provisions of the MPIM and a gross infringement of the Appellant due process rights guaranteed by the federal and state Constitution.

156. Additionally, under 42 C.F.R. § 405.1108, the Council is required to review a request of the ALJ's decision *de novo*. In this case, the Council is, therefore, required by regulations to review both the SSOE and the thirty (30) substantive claims, as well as the applicability of §§ 1870 and 1879 of the Act.

157. In its November 26, 2024 decision, the Council stated that "[s]ince neither CMS nor the appellant challenges the ALJ's individual coverage determinations, limitation on liability determination under § 1879 of the Act, or waiver of overpayment recovery determination under § 1870 of the Act, the Council does not disturb those portions of the ALJ's Decision."

158. However, given that the Council review was a *de novo* review, the Council is obligated to set forth its decisions and the underlying rationales for each issue, and not just those most favorable to the Defendants.

159. Substantively, the Defendants acted arbitrarily and capriciously by wrongfully denying coverage of Interfyl (Q4171), Fluid Flow and Fluid GF (Q4206), and Coretext/Protext (Q4246) and the associated administration claims.

160. The Defendants, likewise, without cause, denied to apply and/or refused to consider the application of limitation of liability provisions under Section 1879 of the Social Security Act for the claims at issue.

161. Generally, in the absence of a controlling NCD or LCD, Medicare contractors must "institute claim-by-claim review to determine whether a claim [for a placental product] meets the reasonable and necessary criteria outlined under section 1862(a)(1)(A) of the Social Security Act, as well as any other applicable requirements for coverage payment in any statute, regulation, or guidance document.".

162. As established in the administrative records, at the time of claims, there was no applicable NCD, LCD, or "statute, regulation, or guidance document" authorizing the Defendants to automatically deny the items/services

as not "safe and effective" and "investigational and experimental". Rather, the Defendants are required to conduct a tailored clinical analysis to determine Medicare coverage. More pertinent to this matter, CMS has issued Technical Direction Letter ("TDL") 220299 which expressly directed all Medicare Contractors to refrain from a wholesale denial of items and services relating to placental products.

163. Under the TDL, CMS mandates the Medicare contractors to conduct a claim-specific clinical analysis based on the beneficiary's unique presentations and conditions. Thus, in order for the Medicare contractors to satisfy their regulatory responsibilities, they must compare the available medical research with the specific diagnosis and treatment regimen for every contested claim. Only then, they may render an individual decision on medical reasonableness and necessity.

164. In the ALJ Decision, Defendants denied coverage for the treatment as not being "reasonable and necessary." A treatment is reasonable and necessary (and thus eligible for Medicare coverage) if it is, *inter alia*, "safe and efficient" and "not investigational or experimental." Medicare Program Integrity Manual (MPIM) § 3.6.2.2. Per the Medicare Appeals Council, these criteria are satisfied "based on authoritative evidence, or alternatively, whether the item or service is

generally accepted in the medical community as safe and effective for the condition for which it is used." In the Case of Int'l Rehab. Scis., Inc. d/b/a Rs Med. (Appellant) (Beneficiaries) Cigna Gov't Services - (Dme Mac - Jurisdiction c) (Contractor) Claim for Supplementary Med. Ins. Benefi, No. Docket Number: M-10-1761, 2011 WL 6284700, at *3 (Unknown State Ct. (Ill.) Mar. 29, 2011).

165. A QIC specifically is required by regulation to provide the provider notice of:

> *A summary of the facts, including as appropriate, a summary of the clinical or scientific evidence used in making the reconsideration; …*
>
> *In the case of a determination on whether an item or service is reasonable or necessary under section 1862(a)(1)(A) of the Act, an explanation of the medical and scientific rationale for the decision[.]*

42 C.F.R. § 405.976(b)(2) & (4). Such analyses are notably absence in the Final Decision. Instead, Defendants utilized a boilerplate "investigational/experimental and non-covered usage" finding without providing any medical or clinical rationale. Clearly, this fails spectacularly of their obligations under § 405.976(b)(2) & (4), as described above. Moreover, the boilerplate denial also fails to conform with the claim-by-claim review requirement pursuant to TDL-220299.

166. Furthermore, during the OMHA appeal process, OIRGV submitted numerous authoritative medical literature and clinical studies for consideration. None of these medical texts were mentioned or discussed in final agency decision. Defendants have failed to properly considered these authoritative texts in rendering its wholesale denials.

167. Particularly, there exists a wealth of authoritative medical literature that proves that human tissue-derived products, such as Interfyl, Fluid Flow/Fluid GF, and Coretext/Protext, are safe and effective for treatment of the type of conditions suffered by the beneficiaries at issue. A number of full-scale clinical studies have proved that such human tissue-derived injections are safe and effective at ameliorating pain associated with osteoarthritis, tendinopathy, plantar fasciitis, and other inflammatory conditions. Notably, the research data showed that placental products containing placenta-derived mesenchymal stromal cells significantly reversed the osteoarthritis progression by protection of cartilage, regulation of anabolic (Col2) and catabolic (MMP13) expressions, and relief of pain symptoms. In 2019, a multicenter randomized controlled single-blind study was conducted among 200 subjects. The study focused on the treatment of osteoarthritis with amniotic suspension allograft (ASA). The evidence presented

in this clinical trial demonstrates that the ASA injection is an effective treatment for the nonoperative management of symptomatic knee osteoarthritis. Clearly, the cited medical literature provides ample evidence concerning the efficacy of placental products for podiatric patients. Importantly, it is consistent with the applicable standards of care to utilize human tissue-derived injections for such musculoskeletal treatment.

168. The administrative records shows that the general consensus among the medical community is that conservative treatments are generally "inadequate, as they do not address the underlying pathology" and are mere "temporary solutions." Due to a number of health and economic constraints, a surgical intervention may not be appropriate for a given patient. In this case, the medical records reflect that conservative treatment was attempted in consistent with the applicable standards of care. Those attempts were proven to ineffective after at least four (4) weeks of efforts. Only then did then OIRGV and the patients opted for the human tissue-derived injection(s). The patients were given full opportunity to ask questions. The procedure was thoroughly explained to the patient in simple terms, thus affording the patient a clear picture of the risks and expectations. All of this was memorialized in the signed consents provided. Importantly, following

each treatment regime, the beneficiaries invariably exhibited marked and objective improvements to the overall conditions and have reported no adverse event. It is, therefore, reasonable and medically necessary for OIRGV to administering Procenta for the beneficiaries.

169. Since the authoritative medical texts submitted satisfy the "safe and effective" and "not experimental or investigational" requirements, and it is undisputed that the administration of these human tissue-derived products is within the accepted standard of medical practice in the local communities, the claim in question must be covered under the Medicare guidelines.

170. Additionally, Defendants erred in finding that Section 1879 of the Social Security Act inapplicable in the instant matter. Under Section 1879, Medicare may properly pay a claim if it is shown that the provider did not know, and could not be expected to know, that the services lacked medical necessity. 42 U.S.C. 1395pp(a).

171. Courts have emphasized whether providers knew of "widely-published" CMS materials governing Medicare coverage (*see MacKenzie Med. Supply, Inc. v. Leavitt*, 419 F. Supp. 2d 766, 774 (D. Md. 2006), aff'd, 506 F.3d 341 (4th Cir. 2007); *Willowood of Great Barrington, Inc. v. Sebelius*, 638 F. Supp. 2d 98, 119 (D.

Mass. 2009)) and whether the provider has received "conflicting information" concerning coverage eligibility (*Yale-New Haven Hosp., Inc. v. Thompson*, 162 F. Supp. 2d 54, 68 (D. Conn. 2001)). The Code of Federal Regulations generally revolves around the acceptable standards of practice in the local medical community, and documents publicly promulgated by CMS about coverage. 42 C.F.R. § 411.406.

172. Furthermore, Medicare Claims Processing Manual, Chapter 30, entitled – Financial Liability Protections, provides that the Social Security Act "protect[s] beneficiaries, healthcare providers, and suppliers under certain circumstances from unexpected liability for charges associated with claims that Medicare does not pay." *See* Section 10. Specifically, Section 1879 of the Act allows for limitation of liability (LOL) where a provider of services did not know, and could not reasonably have been expected to know, that payment would not be made for such the services. In accordance with regulations at 42 CFR 411.406, evidence that the healthcare provider did, in fact, know or should have known that Medicare would not pay for an item or service includes:

> *1. A Medicare contractor's prior written notice to the provider of Medicare denial of payment for similar or reasonably comparable item or service. This also includes notification of Quality Improvement Organization (QIO) screening criteria specific to the condition of the*

beneficiary for whom the furnished item and/or service are at issue and of medical procedures subject to preadmission review by the QIO. Instructions for application of the LOL provision to QIO determinations are in the QIO Manual;

2. Medicare's general notices to the medical community of Medicare payment denial of item or service under all or certain circumstances (such notices include, but are not limited to, manual instructions, bulletins, and Medicare contractors' written guidance);

3. Provision of the item and service being inconsistent with acceptable standards of practice in the local medical community.

4. Written notification from the healthcare provider's utilization review committee informing the healthcare provider or supplier that the item and/or service was not covered;

5. The healthcare provider issuing a written notice of the likelihood of Medicare payment denial for an item and/or service to the beneficiary; or

6. The healthcare provider or supplier being previously notified by telephone and/or in writing that an item or service is not covered or that coverage has ended.

In this case, there are uncontroverted evidence that none of the enumerated scenarios has occurred. There has not been any notification, written or otherwise, from the Medicare contractor concerning the payment eligibility on the products at tissue. Furthermore, there has not been any pervious claim denial for related services.

173. On the contrary, once the first claim was denied, OIRGV immediately ceased all operation relating to human tissue-derived injections. This highlights OIRGV's lack of knowledge on coverage issues. Neither is this the case where Medicare has issued general guidance concerning such injection therapy. Conversely, CMS, in its Transmittal 1024, dated July 15, 2020, specifically added Q4244, Procenta, per 200mg as valid billing code. The CMS's explicit decision to allow for billing of these products signals to providers that Procenta related services are billable under the Medicare guidelines.

174. To make matters worse, the administrative records contain ample evidence that the manufacturer of the products had engaged in a misleading marketing campaign to confuse the providers and boost its sales. Notably, in its promotional materials, the manufacturer repeatedly identified the product as "FDA/TRG 361 Letter on File". In addition, the manufacturer aggressively promotes Procenta for podiatric uses. The misleading marketing tactics give the impression that the product has obtained a FDA/TRG 361 letter for podiatric uses. Given the lack of contravening or competing information on Medicare coverage, it is unreasonable to expect OIRGV to know that the claims will be ultimately denied by the contractor.

175. Clearly, the records established OIRGV has no actual or constructive knowledge of the Medicare coverage for these products. As such, the LOL provision applies and OIRGV cannot be found liable.

176. The Defendants have not produced a scintilla of evidence countering the lack of actual and constructive knowledge on OIRGV's part.

177. Defendants' refusal to apply the LOL provision constitute a gross misapplication of the law.

178. Based on the foregoing, Defendants' final agency order and their decision to deny coverage is not support by substantial evidence, constituted a clear error of law and an arbitrary and capricious act.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgement against Defendants for the following:

1. An Order from this Court invaliding the Secretary's final agency order and overpayment determination; and

2. An Order from this Court requiring Defendants to refund on the principal Plaintiff paid plus interest on the amount recouped; and

Additional Relief Requested.

A. Prejudgment and post-judgment interest;

B. Reasonable attorney's fees and costs of suit; and

C. Such other and further relief as the Court may deem just and proper under law.

CERTIFICATION AND CLOSING

Under Federal Rule of Civil Procedure 11, by signing below, I certify to the best of my knowledge, information, and belief that this Complaint: (1) is not being presented for an improper purpose, such as to harass, cause unnecessary delay, or needlessly increase the cost of litigation; (2) is supported by existing law or by a nonfrivolous argument for extending, modifying, or reversing existing law; (3) the factual contentions have evidentiary support or, if specifically so identified, will likely have evidentiary support after a reasonable opportunity for further investigation or discovery; and (4) the complaint otherwise complies with the requirements of Rule 11.

Dated: January ____, 2025

Respectfully submitted,

RIVAS GOLDSTEIN, LLP

By: */s/ John J. Rivas*

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VERIFICATION

State of Texas)
County of Cameron)

DR. MARIO QUESADA, being duly sworn, deposes and says that I am the owner of Plaintiff, Orthopedic Institute of Rio Grande Valley, PA, in the case captioned *Orthopedic Institute of Rio Grande Valley, PA v. Xavier Becerra, et al*, filed in the United States District Court for the Southern District of Texas, and have authorized the filing of this Complaint. I have reviewed the allegations in the Complaint, and to those allegations of which I have personal knowledge, I believe them to be true. As to those allegations of which I do not have personal knowledge, I relied on the Plaintiff's records pertaining to the billing of Medicare (CMS) for patients, and the information provided by the Defendant agencies, and I believe them to be true.

DR. MARIO QUESADA

STATE OF TEXAS)
COUNTY OF CAMERON)

The foregoing Verification was sworn to before me this 17 day of January 2025, by Dr. Mario Quesada, who [ ] is personally known to me or [ ] has produced Texas D.L. as identification.

[Notary Seal]

MARIBEL PERALEZ
Notary Public
State of Texas
ID # 13433053-4
My Comm. Expires 04-27-2027

Notary Public
Printed Name: Maribel Peralez